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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0359]

Public Meeting--Strengthening the National Medical Device Postmarket Surveillance System; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the following public meeting entitled "Public Meeting--Strengthening the National Medical Device Postmarket Surveillance System." The purpose of the meeting is to solicit public feedback regarding the medical device postmarket surveillance system in the United States.

DATES: The public meeting will be held on September 10, 2012, from 9 a.m. to 4 p.m.

ADDRESSES: The public meeting will be held at the Greenbelt Marriott Hotel, 6400 Ivy Lane, Greenbelt, MD 20770, 301-441-3700.

FOR FURTHER INFORMATION CONTACT: Anita Rayner, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3316, Silver Spring, MD 20993, 301-796-6002, email: Anita.Rayner@fda.hhs.gov; or Danica Marinac-Dabic, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4110, Silver Spring, MD 20993, 301-796-6689, email: Danica.Marinac-Dabic@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending this public meeting must register online by 5 p.m., September 10, 2012. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permits, onsite registration on the day of the meeting will be provided beginning at 8 a.m.

If you need special accommodations due to a disability, please contact Joyce Raines Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4319, Silver Spring, MD 20993, 301-796-5709, email: joyce.raines@fda.hhs.gov. no later than September 5, 2012.

To register for the public meeting, please visit FDA's Medical Devices News & Events--Workshops & Conferences calendar at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this public meeting from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number. Those without Internet access should contact Danica Marinac-Dabic (see Contact Person) to register. Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Meeting: This meeting will also be Webcast. Persons interested in viewing the Webcast must register online by 5 p.m., September 5, 2012. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after September 7, 2012.

Requests for Oral Presentations: This public meeting includes a public comment session and a moderated discussion session. During online registration, you may indicate if you wish to present during a public comment session or participate in a specific session, and which topics you wish to address. FDA has included general topics in this document. FDA will do its best to accommodate requests to make public comment. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, FDA will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will notify participants by September 4, 2012. All requests to make oral presentations must be received by August 31, 2012. Any presentation materials must be emailed (see Contact Person) no later than September 5, 2012. No commercial or promotional material will be permitted to be presented or distributed at the meeting.

Comments: FDA is holding this public meeting to solicit public feedback regarding the medical device postmarket surveillance system in the United States. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the meeting topics. The deadline for submitting comments related to this meeting is October 9, 2012.

Regardless of attendance at the meeting, interested persons may submit either written comments regarding this document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852 or electronic comments to http://www.regulations.gov. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. In

addition, when responding to specific questions as outlined in section II of this document, please identify the question you are addressing. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the meeting on the Internet at http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm. (Select this meeting from the posted events list.)

I. Background

FDA's Center for Devices and Radiological Health (CDRH) is responsible for protecting the public health by assuring the safety and effectiveness of medical devices and safe radiation-emitting products. A key part of this mission is to monitor medical devices and radiological products for continued safety and effectiveness after they are in use and to help the public get the accurate, science-based information they need to improve their health.

Several high-profile device performance concerns have led some to question whether CDRH's current postmarket surveillance system is optimally structured to meet the challenges of rapidly evolving medical devices and the changing nature of health care delivery and information technology. In their report entitled "Medical Devices and the Public's Health: The FDA 510(k)

Clearance Process at 35 Years" published in July 2011, the Institute of Medicine recommended that FDA develop and implement a comprehensive medical device postmarket surveillance strategy to collect, analyze, and act on medical device postmarket performance information. As part of the process of developing and implementing this strategy, FDA is holding a public meeting to discuss the current and future state of medical device postmarket surveillance. Prior to this public meeting, FDA intends to issue a preliminary report on CDRH's plan to strengthen the medical device postmarket surveillance system in the United States. FDA intends to solicit public feedback regarding the report contents.

II. Topics for Discussion at the Public Meeting

We intend to solicit public feedback regarding the medical device postmarket surveillance system in the United States. Specific topics of interest include, but are not limited to, the following: (1) The unique device identifier system and its incorporation into health-related electronic records; (2) national and international device registries for selected products; (3) adverse event reporting and analysis; and (4) developing and using new methods for evidence generation synthesis and appraisal. These topics will also be discussed in relation to the Sentinel provision in the FDA Safety and Innovation Act calling for the expansion of the postmarket risk identification and analysis system to include devices. Key questions for feedback include:

- Are these the right efforts?
- What principles should drive these efforts?
- What are the attributes of an effective “active surveillance” system for devices?
- How can the device active surveillance system leverage existing systems (e.g., Sentinel)?

Following public comment, FDA intends to have a moderated discussion session regarding strengthening the national medical device postmarket surveillance system.

Dated: August 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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